



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,892	07/20/2004	Shigeru Hiramoto	2004-1149A	9008

513 7590 08/02/2006

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT	PAPER NUMBER
----------	--------------

1661

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/501,892	Applicant(s) HIRAMOTO ET AL.	
	Examiner S. B. McCormick-Ewoldt	Art Unit 1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-21 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 15-21 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7-20-04 & 4-11-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1661

DETAILED ACTION

The amendment of May 30, 2006 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Application

The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1661.

Election/Restrictions

Applicant elected species, "animal proteins derived from milk" and "lactose" in the reply filed on February 7, 2006, is acknowledged.

With regard to Applicant's request to the election of species withdrawal since claims 15-21 are silent on the species, it is noted to Applicant that the species are clearly the same as in the species requirement. Therefore, the election of species is maintained and would equally apply to the method claims.

The requirement is still deemed proper and is therefore is made FINAL.

Claims Pending

Applicant has cancelled claims 1-14. Claims 15-21 are pending. Claims 15-21 are examined on the merits solely in regard to the elected species.

Information Disclosure Statement

It appears that PTO Form 1449 (references AI-AN) dated July 20, 2004 was inadvertently left out of the Office action dated March 28, 2006. It has been included with this Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1661

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-17^{are} rejected under 35 U.S.C. 102(e) as being anticipated by Kim *et al.* (US 6,627,238).

Kim *et al.* (US 6,627,238) expressly teach the well-known Maillard reaction, which is combining naturally occurring sugars and proteins and heated (i.e. browning) (column 1, lines 24-30). Kim discloses that lactose could be used as the sugar and casein, an animal protein derived from milk, as the protein. The browning composition of the sugar and protein is used in food products (column 2, lines 4-10). However, by consuming the food (i.e. browning reaction) one would be inherently inhibiting *Helicobacter pylori*. Therefore, the browning reaction of Kim *et al.* meets the limitations of claim 15 and thus anticipates the claimed invention.

Claim Rejections - 35 USC § 103

Claims 15-21, as previously rejected in claims 1-21, remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kim *et al.* (US 6,627,238) in view of Kodama (US 6,828,298) for reasons set forth in the previous Office action which are restated below.

Kim *et al.* (US 6,627,238) discloses the well-known Maillard reaction, which is combining naturally occurring sugars and proteins and heated (i.e. browning) and can be used with an aqueous emulsion. Kim discloses that lactose could be used as the sugar and casein, an animal protein derived from milk, as the protein. The browning composition of the sugar and protein is used in food products (column 1, lines 24-30; column 2, lines 4-10).

Kim does not disclose wherein the product is used as an adhesion inhibitor for *Helicobacter pylori* or wherein the food is raw cow's milk or milk powder or skim milk powder or whey or evaporated milk or wherein the browning reaction is carried out at an absorbance at 405 nm or wherein using the browning reaction of sugar and protein is used with an inhibitor of gastric-acid secretion or other substances capable of eradicating *Helicobacter pylori* such as a

Art Unit: 1661

polyphenol or an antibiotic or an antibody against *Helicobacter pylori* or a polysaccharide or glycoprotein capable of binding to a *Helicobacter pylori* urease or wherein a pharmaceutical composition is used to treat diseases associated with *Helicobacter pylori* or wherein a method for inhibiting *Helicobacter pylori* by administering an effective amount of the product of the browning reaction between sugar and protein.

Kodama (US 6,828,298) discloses a glycoprotein capable of binding to *Helicobacter pylori* urease. Glycoproteins contained in bovine milk include lactoferrin (i.e. animal protein derived from milk). The glycoprotein is used as an inhibitor of *Helicobacter pylori* colonization in the stomach and is useful for treating diseases associated with *Helicobacter pylori*. Kodama also discloses a food which treats diseases caused by or associated with *Helicobacter pylori* in mammals, including humans when consumed in an effective amount. Glycoprotein can be added to foods for special health use or special dietary use. Foods for specified health uses include milk and dairy products. Kodama also disclose that a pharmaceutical composition may further comprise an inhibitor of gastric acid secretion. The combination of glycoprotein and the inhibitor of gastric acid secretion is more effective in eliminating *Helicobacter pylori* from the stomach. (column 2, lines 55-65; column 3, lines 1-11, 56-57; column 5, lines 27-67; column 6, lines 23-26, 66-67; column 7, 1-4).

One of ordinary skill in the art would have been motivated to use the product of the browning reaction between sugar and protein for inhibiting *Helicobacter pylori* adhesion inhibitor would be inherent to the food item. By adding the glycoprotein and gastric acid secretion inhibitor composition of Kodama with a food product, one would gain added benefits from the composition of Kodama. Although none of the references disclose the absorbance at 405 nm, one of skilled in the art would optimize that particular parameter. It was clear from Kim that the well-known Maillard reaction (i.e. the combining of naturally occurring sugars and proteins and heated (i.e. browning)) is routinely in food products. It was further clear from Kodama that a glycoprotein is capable of binding to *Helicobacter pylori* urease and is used as an inhibitor of *Helicobacter pylori* colonization in the stomach and is useful for treating diseases associated with *Helicobacter pylori* and be incorporated into a food product. Therefore, one of ordinary skill in the art would have had a reasonable expectation that by combining the browning reaction between sugar and protein and the glycoprotein and gastric acid secretion inhibitor

Art Unit: 1661

composition with a food product, one would gain added benefits for *Helicobacter pylori* adhesion inhibitor.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues Kim does not disclose or suggest the product of such reaction (i.e. Maillard reaction) is used as an adhesion inhibitor for *Helicobacter pylori* and Kodama discloses a glycoprotein

Applicant argues that Kim does not disclose or suggest the product of such reaction (i.e. Maillard reaction) is used as an adhesion inhibitor for *Helicobacter pylori*. This is not found persuasive because as discussed supra it was clear from Kim that the well-known Maillard reaction (i.e. the combining naturally occurring sugars and proteins and heated (i.e. browning)) is routinely prepared in food products.

Applicant argues that Kodama discloses a glycoprotein capable of binding to *Helicobacter pylori* urease and the browning reaction is a chemical reaction comprising a heating step. This is not found persuasive because as disclosed in Kodama the glycoprotein in bovine milk (i.e. animal protein derived from milk) does not lose its physiological activity due to heat and therefore can be readily recovered and purified from a starting material and it is advantageous with respect to formulations into a food or medicament, processing and storing (column 4, lines 51-57).

Therefore the rejection is proper and is maintained.

Summary

No claim is allowed.

Art Unit: 1661

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiners' supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme


CHRISTOPHER R. TATE
PRIMARY EXAMINER